European Crop Protection

POSITION PAPER
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ECPA Position on REACH Refit Process

Executive Summary

- **ECPA welcomes the opportunity to contribute to the REACH REFIT review 2017.**
- **ECPA has focused its comments on aspects which we believe are unique to the agrochemicals sector. ECPA is aligned with the comments made by other industry sectors such as CEFIC and DUCC.**
- **ECPA wishes to highlight a potential risk of dual regulation of co-formulants used in Plant Protection Products under REACH, and the (yet to be populated) Regulation 1107/2009 (PPPR) Annex III negative list of co-formulants. The potential issue does not lie with REACH itself, but rather the proper co-ordination between different pieces of EU legislation.**
- **REACH data generation and processes apply to all co-formulants, and ECPA considers that these should be used to populate PPPR 1107/2009 Annex III. The potential problem therefore lies with the fact that PPPR 1107/2009 Annex III fails to make proper links with the relevant REACH provisions.**
- **Safeners and synergists are currently subject to dual regulation. Regulation should not take place under REACH, and only under the PPPR.**
- **REACH data generation and processes apply to the substances used in adjuvants, and ECPA considers that this should be used as the basis for the authorisation of adjuvants under the PPPR.**
- **Biocidal products regulation should be modified to avoid dual regulation of biocidal active substances with REACH for in-can preservative use.**
- **ECPA considers that a revision of the REACH legislation at this moment is not appropriate and the majority of the observed shortcomings can be managed without re-opening the core legal text.**

1 ECPA: primarily a downstream user under REACH

The European Crop Protection Association (ECPA) represents those companies primarily manufacturing active substances for use in plant protection products, and formulating finished plant protection products for sale to end users. The main role of ECPA member companies under REACH is thus as Downstream User, with some registrant activities for intermediates, and non-exempt active substances.

The issues identified in this position paper are within scope of the topics identified (C.1, IV, Interface with other legislation) in the Evaluation and Fitness Check Roadmap (COM, 2016), and center around Efficiency (C.2, Efficiency, 3.) and Coherency (C.2, Coherency, 2.).

2 REACH as the Leading Regulation for Chemicals Management

REACH is the primary regulatory mechanism for the generation of data, assessment and demonstration of safe use, and control of chemicals in Europe. Substances subject to REACH may have many industrial and wide-spread applications, but may also find use as co-formulants in plant protection products. Co-formulant manufacturers, working with the crop protection industry, continue to make a high level of investment in ensuring substances have the necessary data and perform appropriate risk assessments to ensure safe use of these substances. To support the risk

assessment of co-formulants under REACH, ECPA has defined use maps and developed a set exposure tools based on both standard PPP and EU TGD methodology[1].

Any change in the current approach leading to assessment of co-formulant uses in plant protection products under both REACH and the PPPR[2] would create a duplication of administrative, financial and technical requirements with no direct beneficial effect on safety to human health or the environment.

It is also important to recognise that any co-formulant assessment under the PPPR in its current form would be very complex and resource intensive without a suitable framework to address:

- Multiple PPP containing any given co-formulant, used for multiple crops, and distributed across multiple dossiers in multiple Member States;
- Multiple applicants for any given co-formulant under the PPPR;
- Multiple co-formulant manufacturers/importers with no role under the PPPR;
- The PPP applicant in most cases will not be a data holder for the co-formulants;
- Data generation and associated data compensation under REACH would still be required due to other non-PPP uses;
- Any potential concerns surrounding a substance which might arise within a PPP context may be of relevance to other industrial sectors, and should not be dealt with in isolation.

The necessary framework to address these issues efficiently has already been developed within the REACH legislation. To evaluate co-formulant uses in PPP under both REACH and PPPR would create dual regulation of these substances, with associated resource impacts on both industry and the Member States, and fail to leverage the work carried out under REACH.

ECPA strongly supports the current situation whereby substances are primarily managed under REACH, as the administratively most efficient approach, and ensuring proportionate costs between all stakeholders. (Roadmap Issue C.2, Efficiency & Coherence)

3 PPPR Annex III – Negative List of Co-formulants

REACH, CLP[3] and PPPR provide adequate control mechanisms for the regulation of co-formulants in PPP.

The following REACH, CLP and PPPR processes should continue to be used to manage co-formulants:

- Harmonised Classification and Labelling directly affects potential uses of a co-formulant, maximum concentrations, and consumer applications.
- The REACH Risk Management Options Analysis (RMOA) process should be used to decide on the relevant REACH, CLP or PPPR processes on a case-by-case basis (e.g. Restriction vs Authorisation vs harmonised classification etc).
- The REACH Evaluation process should be used where further information or investigation of a substance is desired (via CoRAP).
- The REACH Restriction process should be used for substances for which specific controls may be needed to fully protect human health and the environment (e.g. prohibit use in PPP).
- Case-by-case non-approval decisions of PPP formulations under the PPPR.

Furthermore, ECPA proposes that the inclusion of substances used as co-formulants in PPPR Annex III should be based on the conclusions of the REACH Authorisation process:

[1] http://www.ecpa.eu/industry-resources/reach-registration-evaluation-authorisation-and-restriction-chemicals
[2] Plant Protection Products Regulation (EC) 1107/2009
[3] Regulation (EC) 1272/2008 on Classification, Labeling and Packaging of substances and mixtures.

- Recognising that REACH Authorization does not apply to the use of substances in plant protection products, the outcome of this process (Annex XIV listing) should be used as a trigger for the population of Annex III to Regulation 1107/2009 in an appropriate manner.

Aligning Annex III of Regulation 1107/2009 with REACH Annex XIV would:

- Effectively use the Substances of Very High Concern (SVHC) criteria to identify *candidates* for Annex III inclusion.
- Align the RMOA outcome with the PPPR, and avoid the potential for conflict with other REACH control mechanisms (e.g. Annex XVII (Restrictions)). Other control mechanisms cannot be ruled out for a given substance until the European Commission has made a final decision on Authorisation and Annex XIV listing.
- Take maximum advantage of the data generation and assessments completed under REACH, thus streamlining any assessments and decision making started within PPPR context.
- Align PPPR Annex III with substances for which use within the European market is severely limited.
- Allow rapid selection of substances; 31 substances are currently listed in REACH Annex XIV, which could be used to populate PPPR Annex III in an appropriate manner. Further substances are on the Candidate List for Authorisation, and the SVHC Roadmap sets out the approach to screen for further substances until 2020.

Action against substances with co-formulant uses for which a Member State has a concern (PPPR, Article 27) can already be initiated without delay. In such a case, the relevant Competent Authority(s) can prepare a REACH Annex XV dossier, and use the existing REACH Restriction process to exclude use in plant protection products. An example currently in force is the restriction on nonylphenol ethoxylate, listed in REACH Annex XVII.

Alignment of REACH Annex XIV substances as candidates for PPPR Annex III inclusion would maximise the efficient use of REACH processes. (Roadmap Issue C.2, Efficiency & Coherence)

4 PPPR Active Substance Exemption

REACH Article 15(1) exempts approved active substances, including those on several working lists.

ECPA strongly supports the existing scope of PPP active substance exemptions[4], and any changes would unnecessarily increase the administrative and financial burden on the European crop protection manufacturing industry and Member State Authorities, without adding to the protection of human health and the environment. (Roadmap Issue C.2, Efficiency)

5 Safeners and synergists

Harmonised rules for the approval of safeners and synergists, although foreseen, have not yet been set under the PPPR (Article 26). Because REACH Article 15(1) only exempts active substances, REACH registration of new and phase-in safeners and synergists is currently also required. Because safeners and synergists tend to be specialised substances developed solely for plant protection use, manufacture and import should be wholly exempt from REACH for PPP uses, as for other PPP active substances. Any future regulation developed to address PPPR Article 26 should thus ensure that dual regulation is avoided, and falls under the PPPR.

The overlap for safeners and synergists was previously identified in the 2013 REACH Review (COM, 2013). (Roadmap Issue C.2, Efficiency & Coherence)

[4] Guidance on Registration, Version 2.0, May 2012, ECHA.

6 Adjuvants

Harmonised rules for the authorisation of adjuvants have not yet been set under the PPPR (Article 58). The substances used in adjuvants tend to be commodity or specialty chemicals, and are fully subject to REACH with potentially many uses by other industrial sectors. Reflecting this, data generation and assessment of substances contained in adjuvants should primarily occur under the REACH legislation, as the most efficient and holistic regulatory approach. Many of the challenges posed for the regulation of commodity co-formulants also apply to the constituents of adjuvants (applicants are not data holders, data generation and compensation, etc). Any future regulation developed to address PPPR Article 58 should thus ensure that dual regulation is avoided and takes place primarily under REACH for substances, and with product authorisation requirements focused on adjuvant product properties.

ECPA strongly supports the current situation whereby commodity substances are primarily managed under REACH, as the administratively most efficient approach, and ensuring proportionate costs between all stakeholders. (Roadmap Issue C.2, Efficiency & Coherence)

7 Biocidal Product Regulation[5]

Biocidal products are used as in-can preservatives to prevent microbial contamination and growth in PPP. This microbial growth spoils the PPP as it has an impact on the colour, viscosity, smell, and homogenicity of the PPP.

The Biocidal Product Regulation (BPR) regulates active ingredients and biocidal products for use as in-can preservatives under Product Type 6 (PT6). While PT6 covers many in-can preservative uses e.g. the use in paints, PPP use is not currently mentioned.

Furthermore, under the BPR, in-can preservative use is considered to be a treated article, and treated articles within the scope of the PPPR are placed out of scope of the BPR (Article 2(2)i).

REACH regards active ingredients regulated under the BPR as registered when Article 15(2) applies, however, because the in-can preservative use of Biocidal Products in PPP is not covered under the BPR, Article 15(2) of REACH cannot be taken into consideration. Because the PPP use is placed outside the scope of the BPR, it appears that REACH registration of biocidal active substances for the tonnage used as PPP in-can preservatives is thus required (REACH Article 15(2) does not apply).

Considering that PPP applicants are usually not data holders for biocidal active substances, and to avoid dual regulation with REACH, ECPA propose the most efficient approach would be to consider PPP in-can preservative use within scope of the BPR. (Roadmap Issue C.2, Efficiency & Coherence)

References

COM(2013) Commission Staff Working Document, General Report on REACH, European Commission, 2013.

COM(2016) Evaluation and Fitness Check Roadmap, European Commission, 2016.

About ECPA

ECPA acts as the ambassador of the crop protection industry in Europe and represents the industry's European regional network. We promote modern agricultural technology in the context of sustainable development, one which protects the health of humans and the environment, and, in doing so, seek to build understanding of our role on why pesticides are needed, recognition of our

[5] Biocidal Products regulation (EU) 528/2012

contribution towards an affordable healthy diet, competitive agriculture and high quality of life, and uphold informed dialogue about our views, values and beliefs.

- We represent our industry in relevant European fora, towards our major stakeholders and the wider public.

- We lead and co-ordinate a European network of member companies and national associations, who act as our local representatives.

- We endeavour to listen and learn from our stakeholders and the public, and seek to understand their interests, views and perspectives.

ECPA advocates EU policies and legislation that uphold a science and risk-based approach, foster innovation, operate in a predictable and proportionate way, enable the industry to perform efficiently, protect intellectual property and reward the introduction of new technologies and practices, as well as safeguard the production of crops from pests in a way that meets the needs of all people, today and tomorrow

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